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EXAMINER

SAUCIER, S

ART UNIT

PAPER NUMBER

1651

DATE MAILED:

06/08/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/923,783

Applicant(s)

Roser et al.

Examiner

Sandra Saucier

Group Art Unit

1651



☒ Responsive to communication(s) filed on Nov 19, 1997

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims^{1,2-}

☒ Claim(s) 1-10, 23, 26-42, 44-49, 54-59, 61-67, 69-73, 75, and 78-96 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-10, 23, 26-42, 44-49, 54-59, 61-67, 69-73, 75, and 78-96 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5, 9, 19

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1651

DETAILED ACTION

Claims 1-10,¹²⁻23, 26-42, 44-49, 54-59, 61-67, 69-73, 75, 78-96 are pending and are considered on the merits.

Information Disclosure Statement

On the IDS submitted on 11/19/97, items 27-29 have been considered, but are lined through because they are not literature or patent citations suitable for printing on the face of the patent. Items 32 and 33 will be initialed when copies of them are resubmitted as per conversation with S. Lehnhardt on June 3, 1999.

Since that conversation, some of the missing references from the IDS of 11/19/97 have been located and have been initialed on the Form 1449. Copies of all of the IDS forms-1449 associated with this application have been attached to this office action so that applicants can ascertain that no forms are missing.

Claim Rejections - 35 USC § 112

INDEFINITE

Claims 1-10,¹²⁻23, 26-42, 44-49, 54-59, 61-67, 69-73, 75, 78-96 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 57, 58 and 82 depend from a canceled claim.

Claims 1, 62, 70, 91 and 94 recite "thin" foamed glass matrix. However, "thin" is a comparative term without a reference point. How thick is "thin"?

Claims 1, 40, 72, 73, 75, 91 recite "reduced" pressure. "Reduced" is a comparative term with no reference point.

Claim 14 recites "higher than about 25...". This is indefinite because it cannot be determined if the temperature may be 25 when one considers the "about" portion of the modifier or if the temperature must be above 25. Thus the limitation is not clear.

Claim 19 recites "reduced external pressure". Reduced is a comparative term. Also, external to what? What is internal as opposed to external? Please clarify external and internal with regard to the process.

Art Unit: 1651

Claim 26 recites "below about 30..". The metes and bounds of this range cannot be determined because below and about mean two different areas of a range or point. Does 30 fall within the "below about" limitation or must the pressure be less than 30? The claim is indefinite because the boundary cannot be understood.

Claim 30 recites "external temperature...". External to what? Where is the temperature measured?

Claim 65 recites "optionally". It is suggested that a dependent claim be drafted to incorporate the "optional" material and the "optional" phrase be canceled.

Claims 81, 87 recite "small" molecule(s), without a reference point. What is the cutoff between small, medium and large molecules? These are terms of reference and have meaning only with regard to direct comparison of one specific molecule with another specific molecule(s).

The terms above are relative terms which render the claims indefinite. The terms are neither defined by the claim, nor does the specification provide a definition of the terms for ascertaining the requisite degree, thus the metes and bounds of the invention are unclear.

Claims 64, 67 and others recite "different solvent". It is unclear whether for example, water in two different containers, the first container having the polyol and the second container having the biologically active agent fulfills the "different solvent" limitation, or if the solvents must be distinct compounds such as water and ethanol.

NEW MATTER

Claims 14 and 79 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

With regard to claim 79, support exists for the range 10^6 - 10^7 Pascal seconds on page 17, line 11. No support is found for the recitation "at least 10^6 Pa·s". This is a new range, from 10^6 to infinity, which has no support in the as filed specification. Further glasses exist in the range of 10^{14} Pa·s. The

Art Unit: 1651

specification has not taught how a syrup can have a large viscosity value without being a rubber or a glass. Thus, this new insertion is without support.

Claim 14 recites "higher than about 25". This appears to be a new range from 25 to infinity which has no literal support or sufficient exemplification over the range of 25 to infinity in the as filed specification to provide support for this recitation.

Claim Rejections - 35 USC § 102

Claims 1-4, 6, 8, 19, 36, 49, 62-67, 71, 72, 78, 83, 85, 87 91 and 93 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by US 5030469 [1].

The claims are directed to a process comprising:

- a) preparing a mixture of a glass-forming carbohydrate, solvent and a foam-promoting additive,
- b) evaporating the solvent to obtain a syrup,
- c) exposing the syrup to a pressure and temperature that causes foaming to form a foamed glass matrix.

The references are relied upon as explained below.

US 5030469 discloses a process of mixing a sugar solution (glass-forming carbohydrate and solvent which is water) and a foaming-promoter solution together in a vacuum (about 0.5 bars) to which flavorings (biologically active agent) may be added. Bubbles form and the tank may be heated to reduce residual moisture content. (column 5, line 43-57). The product has a stable matrix with small bubbles distributed throughout. Residual drying under vacuum may be performed (see claim 3). Vacuum of about 0.5 bars (375 Torr) is the operating vacuum in the beater. Drying of the residual moisture can take place at lower than 0.5 bars (col. 3, l. 55).

This disclosure satisfies the claimed method because the process is carried out under conditions of pressure and temperature which cause a sugar syrup with a foaming agent to form a stable sucrose foamed product with numerous bubble inclusions and flavoring. This is all the claimed method requires. A biologically active agent may be a flavoring. Flavorings have "flavor" because taste/smell receptors are present in the target organism which are stimulated by the flavoring,

Art Unit: 1651

which are physiologically active compounds. Thus, these compounds known as flavorings have biological activity. Further, on page 7 of the specification, flavoring(s) is a specifically named substance to be preserved and disclosed to be particularly suitable to included in a foamed-glass matrix.

While it is understood the invention as disclosed in the specification, is not a candy making process, the claims are broad enough so that they may be interpreted to read upon candy-making or confection art, which is an old art, and they should be carefully revised to avoid this unfavorable interpretation.

All of the active steps are the same, thus the results would reasonably be expected to be the same, formation of a stable, foamed glass matrix with a flavoring.

This reference may be overcome by showing that (1) a sucrose syrup would not boil at room temperature under a vacuum of 0.5 barr as described in col. 5, l. 44, or (2) that under the conditions described, the sucrose-foaming agent mixture described in the patent '469 would not form a glass when it is processed through the secondary drying process and returned to atmospheric pressure and room temperature, as described in the patent '469, or (3) by amending the claims to avoid the inclusion of flavorings, such as using the phrase, "A method for producing a foamed glass matrix containing a pharmaceutically effective substance, therapeutic agent or a prophylactic agent"....., or (4) other persuasive evidence or amendments to the claims.

Cancel Claims 73, 75 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by US 4855326 [1] or WO 89/06542 [1].

The compositions claimed are product by process claims where the composition comprising a glass forming agent and a biologically active agent are dissolved. This process necessarily produces a liquid.

US 4855326 discloses a composition comprising a biologically active compound and a glass forming substance which are dissolved in water (cols. 7-8 and 10, line 40).

WO 89/06542 discloses a composition of trehalose, virus reconstituted in a solvent (see examples).

Art Unit: 1651

Once the glass-forming agent and the biological agent are dissolved in a solvent such as water, they cannot be distinguished from prior art compositions. A product by process claim is treated in the examination process, as a product regardless of the method of manufacture. Once dissolved, the product loses its form. The composition of a sugar and a biological agent in water is the same no matter what the method of manufacture.

A suggested claim follows:

A method for producing a foamed glass matrix comprising the steps of:

- (a) preparing an initial mixture comprising at least one glass matrix-forming material and a solvent therefor,
- (b) evaporating a portion of the solvent from the mixture to obtain a syrup,
- (c) boiling the syrup under less than atmospheric pressure to produce foaming of the syrup,
- (d) continuing step (c) until the boiling results in the formation of a solid foam and producing a foamed glass matrix.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. **Status inquiries must be directed to the Service Desk at (703) 308-0196.** The numbers of the Fax Center for the faxing of papers are (703) 308-4242 and (703) 305-3014.



Sandra Saucier
Primary Examiner
Art Unit 1651
June 4, 1999